

### **REMARKS**

This Amendment is responsive to the Office Action dated March 3, 2006. Applicant has amended claim 4 and added new claims 27-29. Claims 1-29 are pending upon entry of this Amendment.

#### **Allowable Subject Matter**

The Office Action indicated that claims 3, 11 and 20 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, the Office Action also rejected claims 3, 11, and 20 under 35 U.S.C. 102 in view of Cimochoowski et al. and Pool et al. In light of this inconsistency, it is unclear whether the Office Action intended to indicate allowability of claims 3, 11 and 20. Applicants respectfully request clarification of this issue.

In the meantime, in this Amendment, Applicants have added new claims 27-29 to rewrite claims 3, 11 and 20 in independent form. Claim 27 includes all the features of dependent claim 3 and any intervening claims rewritten in independent form, claim 28 includes all the features of dependent claim 11 and any intervening claims rewritten in independent form, and claim 29 includes all the feature of dependent claim 20 and any intervening claims rewritten in independent form.

#### **Claim Rejection Under 35 U.S.C. § 112**

The Office Action rejected claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants have amended claim 4 for purposes of clarification. Claim 4 now recites the antenna comprising a cable for connection of the antenna to the medical device programmer. Applicants submit that claim 4, as amended, meets the requirements of 35 U.S.C. 112, second paragraph.

#### **Claim Rejection Under 35 U.S.C. § 102**

The Office Action rejected claims 1-4, 7, 18-20, 23 and 25 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,697,986 to Cimochoowski et al. ("Cimochoowski"). The

Office Action also rejected claims 9, 10-12, 15, 18-10 and 23 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,561,975 to Pool et al. ("Pool"). Applicants respectfully traverse the rejections. The cited references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. 102(b) and 102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

***Cimochowski***

Applicants' independent claims 1 and 18 recite an antenna for a medical device programmer that defines an aperture with a channel formed to hold a portion of an item of clothing associated with a patient and thereby hold the antenna in a substantially fixed position relative to an implantable medical device.

In support of the rejection, the Office Action stated that Cimochowski teaches an antenna with a ring-like structure that defines both a channel and an aperture because an aperture is defined as an opening as a hole, gap, or slit, and a channel is defined as a course though which something can be directed or moved. The Office Action further asserted that the ring-like antenna structure described by Cimochowski is capable of holding a portion of clothing associated with a patient due to the fact that clothing can be placed within the opening, and in turn hold the ring-shaped antenna in a relatively fixed position relative to an implanted medical device.

Applicants believe that the Office Action misinterpreted the scope and content of the Cimochowski reference for at least two reasons. First, Cimochowski fails to teach or suggest an antenna that defines an aperture with a channel formed to hold a portion of an item of clothing. As the Office Action acknowledged, Cimochowski describes an antenna comprising an external coil with a ring-like structure such that the antenna defines a circular aperture. The circular aperture described by Cimochowski does not provide any channel that is formed to hold a portion of clothing.

The Office Action stated that the ring-like structure of the antenna defines both an aperture and a channel. However, Applicants' claims require an aperture with a channel, and further specify that the channel is formed to hold a portion of an item of clothing. The Office Action referred to definitions of the terms "aperture" and "channel" in support of the

interpretation of Cimochoowski. However, the analysis of the Office Action fails to take into account other definitions of the term “channel” and the usage of the term “channel” in Applicants’ own disclosure. Specifically, the term “channel” may also be defined as a trench, furrow or groove, (Dictionary.com). In addition, paragraph [0095] of Applicants’ specification states that the antenna has an aperture with a narrow, tapered end that defines a channel or “notch” designed to capture clothing worn by the patient. Applicants’ FIG. 6A illustrates the antenna 34 including a telemetry head 74 that defines an aperture 78 with a narrow, tapered end 82. In addition, Applicants’ FIG. 6B illustrates the telemetry head 74 of the antenna 34 in which part of a patient’s shirt is held in place within the channel defined by the narrow, tapered end 82 of the aperture 78.

Cimochoowski does not describe an antenna with a channel, groove, notch, or any other structure that is capable of holding a portion of an item of clothing. Instead, Cimochoowski describes a stent implanted within an artery within a thigh of a patient that includes an RF antenna, and an external coil antenna that includes a plurality of turns sufficient in diameter to encompass the thigh of a patient. Cimochoowski further states that the external coil antenna can be made sufficiently large to encompass the portion of the body in which the implanted stent is disposed, such as the torso, another limb of the patient, or the neck of the patient, (Col. 16, ll. 1-16). Clearly, Cimochoowski describes an antenna having a wide, open aperture capable of wrapping around relatively large portions of a patient’s body, and makes no mention of any structure resembling a channel that is formed to hold a portion of clothing.

Contrary to the assertion of the Office Action, merely being able to place an item of clothing through the aperture of the external coil antenna does not equate to holding the item of clothing, and does not address the absence of structure resembling a channel formed in the aperture of the antenna. An antenna with an aperture large enough to encircle a body part of a patient, as described in the Cimochoowski reference, is clearly too large to hold a portion of an item of clothing without the item of clothing slipping out of the aperture. Consistent with the lack of any channel structure, the Cimochoowski reference makes no mention of holding a portion of an item of clothing within the aperture of the external coil antenna, as recited by Applicants’ independent claims 1 and 18.

Second, Cimochoowski does not describe attaching an antenna to a portion of an item of clothing of a patient to hold the antenna in a substantially fixed position relative to an implantable medical device. As described above, Cimochoowski fails to even mention attaching the antenna to an item of clothing of the patient. Instead, Cimochoowski merely discusses using the large, circular aperture of the external coil antenna to encompass or encircle the portion of the body of the patient in which the implanted stent is disposed. Cimochoowski does not teach an antenna capable of holding a portion of an item of clothing of a patient in order to position the antenna relative to an implantable medical device within the patient.

Applicants' claimed invention requires positioning the antenna in a substantially fixed position relative to an implantable medical device in order to communicate with the implantable medical device. On the contrary, Cimochoowski describes the external coil antenna positioned to encircle the implanted stent in order to power and receive signals from the stent. The Cimochoowski reference specifically states, "[c]oupling is maximized between external coil 154 and RF antenna 30" used on the stent when the central axes of both the RF antenna and the external coil are coaxially aligned...coupling is minimized when the central axes of the external coil is perpendicular to the axes of the RF antenna," (Col. 16, ll. 16-27, emphasis added).

Cimochoowski teaches an antenna with an aperture sized to encompass a portion of the body of a patient in order to communicate properly with the implanted stent. Clearly, the antenna taught by the Cimochoowski reference requires positioning around the implanted stent by encompassing a body part of a patient. Indeed, it appears that the antenna described by Cimochoowski would not operate as intended with the implanted stent when merely positioned relative to the implanted stent. This is further evidence that the antenna described by Cimochoowski is not constructed to hold an item of clothing of the patient.

In regard to Applicants' independent claim 25, the Examiner applied the same arguments as to independent claims 1 and 18 discussed above. Applicants' claim 25 recites an antenna for a medical device programmer comprising an antenna head, and means for attaching the antenna head to an item of clothing associated with a patient and thereby hold the antenna in a substantially fixed position relative to an implantable medical device.

As described above, Cimochoowski does not describe attaching an antenna head to an item of clothing of a patient to hold the antenna in a substantially fixed position relative to an

implantable medical device. On the contrary, Cimochoowski describes an external coil antenna positioned to encircle the implanted stent in order to power and receive signals from the stent. Clearly, the antenna taught by the Cimochoowski reference requires positioning around the implanted stent by encompassing a body part of a patient. Cimochoowski does not describe means for attaching an antenna head to an item of clothing to position the antenna relative to an implantable medical device. It appears that the antenna described by Cimochoowski would not operate as intended with the implanted stent when merely positioned relative to the implanted stent. Again, the antenna described by Cimochoowski is not constructed to hold an item of clothing of the patient.

Furthermore, in regard to Applicants' dependent claims 2 and 19, which recite that the aperture comprises a wide end to insert the portion of the item of clothing, the Office Action stated that the ring-shaped antenna described by the Cimochoowski reference inherently possesses a wide end that can be used for insertion of clothing. It appears that the Office Action has equated the entire aperture of the ring-shaped antenna from Cimochoowski as a wide end of the aperture through which clothing may be inserted. Applicants are confused by the assertion by the Office Action because the Office Action also equated the aperture of the ring-shaped antenna with a channel of the aperture to hold clothing. Accordingly, it does not seem appropriate to characterize the aperture in Cimochoowski as forming both a wide end and a channel, when in fact all Cimochoowski discloses is a circular aperture.

Applicants' invention as defined in claims 2 and 19 clearly recites an antenna with an aperture that includes the separate components of a channel formed to hold an item of clothing and a wide end to insert the item of clothing into the aperture. Cimochoowski fails to teach or suggest an antenna with an aperture defining any shape other than a large, circular opening to encompass a body part of a patient. Cimochoowski does not describe an antenna with an aperture including both a channel and a wide end for the insertion and holding of an item of clothing. Furthermore, the Cimochoowski reference fails to teach each and every feature of Applicants' independent claims 1 and 18, from which claims 2 and 19 depend.

In reference to Applicants' dependent claims 3 and 20, the Office Action stated that if the external coil antenna described by Cimochoowski were held vertically and rotated about its vertical axis, the aperture of the antenna would appear to be much thinner than the aperture of the

antenna when not rotated. The curious reliance by the Office Action on appearance given a particular visual perspective bears no relationship to the actual structure of the Cimochoowski antenna, and amounts to a mere contrivance to side-step the limitations of Applicants' claims. Moreover, the Office Action indicated that Applicants' claims 3 and 20 would be allowable if rewritten in independent form. Applicants note this inconsistency and request clarification.

Applicants' claims 3 and 20 clearly recite an antenna with an aperture that includes the separate components of a channel formed to hold an item of clothing and a wide end to insert the item of clothing into the aperture, wherein the channel is substantially narrower than the wide end of the aperture. Whether the antenna aperture appears to be wide or have a channel when rotated is completely irrelevant to the actual structure of Applicants' claims. Furthermore, merely rotating an antenna such that an aperture of the antenna appears narrower does not enable an item of clothing to be inserted through the aperture before rotating the antenna and then held in the aperture upon rotating the antenna. Applicants request that the Office Action focus on the actual structural requirements of the claims and the actual structural features of the Cimochoowski reference, rather than imaginary structure or other contrivance resulting from optical illusion.

Applicants' dependent claims 7 and 23 recite that the aperture comprises a wide end with a tear drop-like shape to insert the portion of the item of clothing. The Office Action stated that referring to an object or orifice as "teardrop shaped is quite broad considering the fact that a teardrop can be a multitude of shapes considering its environment." However, the Office Action did not apply the ordinary meaning of the term "tear drop" nor the meaning of the term set forth in Applicants' specification that define a tear drop to be shaped similar to a falling drop of water. Specifically, paragraph [0094] of Applicants' specification states, "The loop-like telemetry-head may define a unique aperture 78 with a wide end 80 and a narrow, tapered end 82, e.g., somewhat similar to the shape of a tear drop."

As described above, Cimochoowski fails to teach or suggest an antenna with an aperture defining any shape other than a large, circular opening to encompass a body part of a patient. Those skilled in the art would understand the tear drop shape to be a shape identical or similar to that described above, given common usage of the term "tear drop" and the meaning attributed to the term in Applicants' disclosure. Cimochoowski does not describe an antenna with an aperture including both a channel and a wide end with a tear drop-like shape for the insertion and holding

of an item of clothing. Furthermore, the Cimochoowski reference fails to teach each and every feature of Applicants' independent claims 1 and 18, from which claims 7 and 23 depend.

In order to support an anticipation rejection under 35 U.S.C. 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."<sup>1</sup> If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. 102(b) is improper.<sup>2</sup>

Cimochoowski fails to disclose each and every limitation set forth in claims 1-4, 7, 18-20, 23 and 25. For at least these reasons, the Office Action has failed to establish a prima facie case for anticipation of Applicants' claims 1-4, 7, 18-20, 23 and 25 under 35 U.S.C. 102(b). Withdrawal of this rejection is requested.

### *Pool*

Applicants' independent claim 9 defines a method comprising positioning an antenna relative to an implanted medical device, wherein the antenna defines an aperture with a channel, and pulling a portion of an item of clothing through the channel in the antenna to thereby hold the antenna in a substantially fixed position relative to the implantable medical device. In support of the rejection, the Office Action stated that Pool teaches an antenna housed within a belt, and that such a housing inherently possesses the ability to have clothing pulled through the channel created by buckling the belt, thereby holding the antenna in a substantially fixed position relative to the implanted device.

Applicants believe that the Office Action has misinterpreted the scope of the Pool reference. Pool fails to teach or suggest positioning an antenna relative to an implantable medical device by pulling a portion of an item of clothing through a channel defined by an aperture of the antenna to hold the antenna relative to the implantable medical device.

Instead, Pool describes a wearable telemetry arrangement for communicating with an implantable medical device that includes an article to be physically coupled to and donned on a

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<sup>1</sup> See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").

<sup>2</sup> *Id.* See also *Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

body and an antenna member located on the article. For example, the Pool reference describes the wearable article as a shirt or a similar type of vestment with the antenna member in the form of a telemetry antenna band disposed along the perimeter of the vestment (Col. 7, ll. 3-9). In addition, Pool states that, "Other wearable articles that can be donned on the body of the patient, that house an antenna band include, but are not limited to, a belt, a patch that adheres to a patient, a sheet that lays on a patient, a portable module and an article of jewelry," (Col. 8, ll. 33-37).

Clearly, Pool describes an antenna disposed within an article that a patient may wear such that an aperture of the antenna surrounds the portion of the patient's body in which the implantable medical device is implanted. Therefore, the shape of the article in which the antenna is disposed defines the shape of the aperture of the antenna. In the case of a buckled belt, the antenna has a wide, open aperture capable of wrapping around a patient's waist. The Pool reference does not describe the aperture of the antenna defining a channel thorough which to pull a portion of an item of clothing to hold the antenna relative to an implantable medical device, as recited by Applicants' independent claim 9.

Contrary to the assertion by the Office Action, buckling a belt in which the antenna described by Pool is disposed does not create a channel through which to pull a portion of an item of clothing to hold the antenna relative to the implantable medical device. Pool teaches an antenna being included in a wearable article with the ability to hold the antenna relative to the implantable medical device when a patient wears the article in which the antenna is disposed. Therefore, the antenna within the belt, as described by Pool, is positioned relative to an implantable medical device by buckling the belt around the patient's waist, not by pulling an item of clothing through the buckled belt. In other words, a belt is wrapped about a person. The person is not pulled through a belt, much less through a channel in an aperture of an antenna. The interpretations of both the method of claim 9 and the Pool reference by the Office Action are so unreasonably broad as to be implausible.

In regard to Applicants' independent claim 18, the Office Action applied similar arguments as to independent claim 9 discussed above. Pool does not describe an antenna defining an aperture with a channel formed to hold a portion of an item of clothing associated with a patient and thereby hold the antenna in a substantially fixed position relative to an implantable medical device, as recited by Applicants' claim 18.



As described above, Pool describes an antenna disposed within an article, such as a belt, that a patient may wear such that the shape of the article in which the antenna is disposed defines the shape of the aperture of the antenna. In the case of a buckled belt, the antenna has a wide, open aperture capable of wrapping around a patient's waist. The antenna described by Pool does not define a channel formed to hold an item of clothing. The wearable article in which the antenna of the Pool reference is disposed has the ability to hold the antenna relative to the implantable medical device when a patient wears the article in which the antenna is disposed. Therefore, the antenna within the belt, as described by Pool, is positioned relative to an implantable medical device by buckling the belt around the patient's waist, not by attaching the buckled belt to an item of clothing.

Furthermore, in regard to Applicants' dependent claims 10 and 19, which recite that the aperture comprises a wide end to insert the portion of the item of clothing, the Office Action stated that the antenna described by the Pool reference inherently possesses a wide end to pull clothing through. It appears that the Office Action has equated the entire aperture of the antenna from Pool as a wide end of the aperture through which clothing may be inserted. Applicants are confused by the assertion by the Office Action because the Office Action early equated the aperture of the antenna as a channel of the aperture to hold clothing.

Applicants' invention as defined in claims 10 and 19 clearly recites an antenna with an aperture that includes the separate components of a channel formed to hold an item of clothing and a wide end to insert the item of clothing into the aperture. Pool fails to teach or suggest an antenna with an aperture defining a wide end and a channel for the insertion and holding of an item of clothing of a patient. Furthermore, the Pool reference fails to teach each and every feature of Applicants' independent claims 9 and 18, from which claims 10 and 19 depend.

In reference to Applicants' dependent claims 11 and 20, the Office Action stated that if the belt like housing of the antenna described by Pool were held vertically and rotated about its vertical axis, the aperture of the antenna would appear to be much thinner than the aperture of the antenna when not rotated. The curious reliance by the Office Action on appearance given a particular visual perspective bears no relationship to the actual structure of the Pool antenna, and amounts to a mere contrivance to side-step the limitations of Applicants' claims. Moreover, the

Office Action indicated that Applicants' claims 11 and 20 would be allowable if rewritten in independent form. Applicants note this inconsistency and request clarification.

Applicants' claims 11 and 20 clearly recite an antenna with an aperture that includes the separate components of a channel formed to hold an item of clothing and a wide end to insert the item of clothing into the aperture, wherein the channel is substantially narrower than the wide end of the aperture. Whether the antenna aperture appears to be wide or have a channel when rotated is completely irrelevant to the actual structure of Applicants' claims. Furthermore, merely rotating an antenna such that an aperture of the antenna appears narrower does not enable an item of clothing to be inserted through the aperture before rotating the antenna and then held in the aperture upon rotating the antenna. Applicants request that the Office Action focus on the actual structural requirements of the claims and the actual structural features of the Pool reference, rather than imaginary structure or other contrivance resulting from optical illusion.

Applicants' dependent claims 15 and 23 recite that the aperture comprises a wide end with a tear drop-like shape to insert the portion of the item of clothing. The Office Action stated that referring to an object or orifice as "teardrop shaped is quite broad considering the fact that a teardrop can be a multitude of shapes considering its environment." As discussed above, the Office Action did not apply the ordinary meaning of the term "tear drop-like" nor the meaning of the term set forth in Applicants' specification that define a tear drop to be shaped similar to a falling drop of water.

Those skilled in the art would understand the tear drop shape to be a shape identical or similar to that described above, given common usage of the term "tear drop" and the meaning attributed to the term in Applicants' disclosure. Pool does not describe an antenna with an aperture including both a channel and a wide end with a tear drop-like shape for the insertion and holding of an item of clothing. Furthermore, the Pool reference fails to teach each and every feature of Applicants' independent claims 9 and 18, from which claims 15 and 23 depend.

Pool fails to disclose each and every limitation set forth in claims 9, 10-12, 15, 18-20 and 23. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicants' claims 9, 10-12, 15, 18-20 and 23 under 35 U.S.C. 102(e).  
Withdrawal of this rejection is requested.

**Claim Rejection Under 35 U.S.C. § 103**

The Office Action rejected claims 5, 6, 8, 16, 21, 22, 24 and 26 under 35 U.S.C. 103(a) as being unpatentable over Cimochoowski. The Office Action also rejected claims 13, 14, 21 and 22 under 35 U.S.C. 103(a) as being unpatentable over Pool. Applicants respectfully traverse the rejections. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

***Cimochoowski***

In support of the rejection, the Office Action stated that although the Cimochoowski reference does not describe the features of Applicants' claims 5, 6, 8, 16, 21, 22, 24 and 26, it would have been obvious to one of ordinary skill in the art to modify the antenna taught by Cimochoowski to include the features. As described above, Cimochoowski fails to teach or suggest an antenna that defines an aperture with a channel formed to hold a portion of an item of clothing to hold the antenna in a substantially fixed position relative to an implantable medical device, as required by Applicants' independent claim 1 and 18. In addition, Cimochoowski does not describe a means for attaching an antenna head to an item of clothing of a patient to hold the antenna in a substantially fixed position relative to an implantable medical device, as required by Applicants' independent claim 25. Therefore, even if the antenna taught by the Cimochoowski reference were modified as suggested by the Office Action to include the features of Applicants' dependent claims, it would not result in Applicants' invention as claimed.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicants' claims 5, 6, 8, 16, 21, 22, 24 and 26 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

***Pool***

In support of the rejection, the Office Action stated that although the Pool reference does not describe the features of Applicants' claims 13, 14, 17, 21, 22 and 26, it would have been obvious to one of ordinary skill in the art to modify the antenna taught by Pool to include the features. As described above, Pool fails to teach or suggest positioning an antenna relative to an

implantable medical device by pulling a portion of an item of clothing through a channel defined by an aperture of the antenna to hold the antenna relative to the implantable medical device, as required by Applicants' independent claim 9. In addition, Pool does not describe an antenna defining an aperture with a channel formed to hold a portion of an item of clothing associated with a patient and thereby hold the antenna in a substantially fixed position relative to an implantable medical device, as required by Applicants' independent claim 18. Therefore, even if the antenna taught by the Pool reference were modified as suggested by the Office Action to include the features of Applicants' dependent claims, it would not result in Applicants' invention as claimed.

For at least these reasons, the Office Action has failed to establish a prima facie case for non-patentability of Applicants' claims 13, 14, 17, 21, 22 and 26 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

#### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed agent to discuss this application.

Date:

6/5/06

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